BTEC Assignment Brief

Qualification	Pearson BTEC International Level 3 Foundation Diploma in Applied Science Pearson BTEC International Level 3 Diploma in Applied Science Pearson BTEC International Level 3 Diploma in Biomedical Science Pearson BTEC International Level 3 Diploma in Environmental Science Pearson BTEC International Level 3 Extended Diploma in Applied Science Pearson BTEC International Level 3 Extended Diploma in Biomedical Science Pearson BTEC International Level 3 Extended Diploma in Environmental Science
Unit number and title	**Unit 5: Principles and Applications of Biology II**
Learning aim(s)	**C:** Examine the development of innovative and future types of treatment for physiological and psychological diseases and disorders.
Assignment title	**Drug development and patient safety**
Assessor	
Issue date	
Hand in deadline	

Vocational Scenario or Context	You are entering a competition that is run annually to encourage young people to develop their skills and confidence in all areas of STEM (Science, Technology, Engineering and Maths). Entry to the competition requires you to complete project-based work that is linked to a specific STEM discipline. Your project is linked to the Pharmaceutical Science industry and will examine the development of treatments for physiological illnesses. You will look at the problems that can arise during the development and testing of new treatments and the ethical, legal and moral issues linked to the development and testing of new pharmaceutical products or other treatments.

Task	As part of your portfolio of evidence you must: ● **Evaluate** the ethical, legal and moral issues related to drug/medicine development and testing and the treatments for **one** physiological disease/disorder or **one** psychological disease/disorder. Your evaluation must include information relating to the current and future challenges faced by medical professionals in ensuring patient safety, minimising risks and avoiding potential harm when delivering healthcare to patients. You must demonstrate a clear understanding of the difference between ethics and morals. Evidence could be presented as a case study. ● **Discuss** the problems and challenges that could arise during the development and testing of new and innovative treatments (new medicines, gene therapy, stem cell therapy, surgical techniques) for **either** a physiological **or** a psychological disease or disorder. You could consider factors such as:

	○ the time and costs involved, ○ heterogeneity (variable results) of treatment effects in clinical trials, ○ animal models as predictors of human responses, ○ regulatory requirements. Ethical, moral and legal aspects of the development will need to be considered. ● Identify **one** named drug/medicine produced from a natural source (plant, animal or microbe) and **one** named drug which has been synthesised for a named disorder/treatment. **Describe** how the **two** drugs were discovered/synthesised. Briefly outline how the bio-active compounds were isolated, analysed and used to form a medicine (the drug development pathway). You should outline and briefly describe any modifications made to the molecules and why these modifications were carried out. Include brief details of the diseases or disorders that the drugs or medicines are used to treat. You must briefly **describe** how medicines are tested, including *in vitro* and *in vivo* tests and clinical trials. You must describe the use of RCT (randomly controlled trials), blinding and placebos. You must also check that you only refer to tests that are currently used. Your evidence could be presented as a leaflet/pamphlet/booklet. Correct scientific terminology must be used and sources must be referenced.
Checklist of evidence required	Your project must include: ● An evaluation of the challenges faced by medical professionals in relation to preventing harm, caused by the process of health care itself ● An evaluation of the ethical, legal and moral issues related to the use of drugs/medicines and treatments ● A discussion of problems that can arise during drug/medicine and treatment development and testing ● A description of the development and testing of a natural and synthetic drug or medicine

Criteria covered by this task:	
Unit/Criteria reference	To achieve the criteria, you must show that you are able to:
C.D3	Evaluate the ethical, legal and moral issues of drug/medicine development, testing and treatments for a physiological or a psychological disease or disorder.
C.M3	Discuss the problems that may arise during development and testing of drugs, medicines and treatments.
C.P3	Describe the development and testing of a drug/medicine derived from a natural source and one that has been synthesised for a specific purpose.
Sources of information	https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process

to support you with this Assignment	https://www.diabetes.org.uk/diabetes-the-basics/diabetes-treatments http://scitechconnect.elsevier.com/plant-to-pill-turn-plant-medicine/ https://www.ncbi.nlm.nih.gov/books/NBK195047/ https://www.gmc-uk.org/-/media/documents/first-do-no-harm-patient-safety-in-undergrad-education-final_pdf-62483215.pdf https://www.alzheimers.org.uk/research/our-research/research-projects/using-innovative-drug-screening-method-identify-potential-new-treatments-alzheimers-disease https://www.reactgroup.org/news-and-views/news-and-opinions/year-2017/the-ethics-of-antibiotic-resistance/
Other assessment materials attached to this Assignment Brief	e.g. work sheets, risk assessments, case study